INSTITUTE FOR WOMEN'S POLICY RESEARCH
1707 L Street NW, Suite 750 • Washington, DC 20036

June 27, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockville, MD 20852

Re: FDA Regulation of Oral Contraceptive Drug Products

Dear Colleagues,

The Institute for Women's Policy Research (IWPR) would like to submit comments supporting the switch of oral contraceptives from prescription status to over-the-counter status. Enclosed is an IWPR issue paper "Evaluating an Rx-to-OTC Switch of Oral Contraceptives: A Cost-Benefit Analysis" written by IWPR Research Fellow Holly Mead, which analyzes the costs and benefits of such a proposal, and which strongly supports the prescription to over-the-counter (Rx-to-OTC) switch of the product.

The cost-benefit analysis found the net benefits to society of an Rx-to-OTC switch of oral contraceptives (OCs) would total approximately $2.06 billion, stemming mostly from the medical cost savings of averted pregnancies. The estimate is calculated by weighing the benefits of the switch, including reduced rates of unintended pregnancy, the health benefits associated with OC use and the opportunity and monetary costs to women of the required physician visit for Rx OCs, against the costs, which include health risks associated with OC use, higher incidences of adverse events in at-risk women, the increased risk of undiagnosed disease to those women who forego annual gynecological exams and the increased cost to pharmaceutical companies of marketing OTC oral contraceptives.

With the availability of oral contraceptives over-the-counter, access to this important form of contraception would reduce rates of unwanted term pregnancies, the most expensive outcome of an unplanned pregnancy. In addition, OTC OCs would reduce the rates of abortion, miscarriages and ectopic pregnancies. Total savings from these reductions equal close to $2.08 billion. An additional $842.53 million in savings would come from the monetary and time costs women would save if distribution of the Pill were released from the direction of a physician. Society would also save approximately $84.5 million in medical costs from the protective health benefit of the Pill, including lower incidences of pelvic inflammatory disease, benign

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breast disease, ovarian cysts, ovarian cancer and endometrial cancer. In total the benefits to society equal approximately $5.18 billion.

The savings associated with OTC OCs are offset slightly by the costs associated with greater use of the drug. For example, one potential risk is that some women would forego their annual gynecological exams if OCs were available over-the-counter, which could lead to delayed diagnosis and treatment of health conditions such as early stage cancers. IWPR estimates that costs associated with this risk would total approximately $407.2 million. The increased risk of adverse health events in the general population of OTC OC users would cost society $44.6 million in added medical costs and the increased risk of adverse events in at-risk women would cost society about $83.8 million in medical costs. Finally, the expense of marketing an OTC birth control pill could reach as much as $405 million in ad/promo costs. Total costs to society would approximate $3.11 billion.

The benefits of an OTC oral contraceptive, however, outweigh the costs by almost 70 percent. Based on these results, IWPR would strongly urge the Committee to consider the substantial societal benefit of OTC OCs when making its final decision regarding their Rx-to-OTC switch.

The Institute for Women's Policy Research is a public policy research organization dedicated to informing and stimulating the debate on public policy issues of critical importance to women. The Institute has conducted research on access to health insurance, the costs and benefits of preventive health services and the costs of domestic violence. IWPR Research Fellow Holly Mead has an extensive background in the area of women's health and the Food and Drug Administration, beginning her career as a reporter and editor for FDC Reports, which publishes a number of trade journals covering the FDA. She is now pursuing her PhD in public policy with an emphasis on women's health. Please do not hesitate to call me if you have any questions about this report or if the Institute can provide you with any further information.

Sincerely,

Barbara Gault

Barbara Gault, PhD
Associate Director of Research

EVALUATING AN Rx-TO-OTC SWITCH OF ORAL CONTRACPETIVES

A Cost-Benefit Analysis

Holly Mead
Institute for Women's Policy Research
June 27, 2000

Introduction

Reducing the rate of unintended pregnancies and abortions has been an important policy issue in the past decade. In particular, averting unwanted pregnancies in at-risk populations such as teenage girls, low-income women and women without insurance has been a policy priority for most reproductive rights advocates. Yet, this issue continues to plague the U.S. Approximately 3.6 million pregnancies (56 percent of all pregnancies) were unintended in 1988 (Henry J. Kaiser Family Foundation 1996). Birthrates for women between the ages of 15-17 grew by 24 percent from 1986 to 1993. Eight in 10 pregnancies to women under age 20 were unplanned. Abortion rates are highest among women under age 30, poor women, single women and minority women (Henry J. Kaiser Family Foundation 1996)

Allowing women to choose the timing and spacing of pregnancies helps prevent many unplanned pregnancies. In the U.S., however, access to safe and effective contraception has always been a struggle. Methods of birth control are fewer in number in the U.S. and are often harder to obtain than in other industrialized countries (Samuels *et al.* 1994). Birth control has only been legally allowed since 1965, when the Supreme Court ruled in *Griswold v. Connecticut* that married women were allowed to use contraceptives. It was not until the 1972 Supreme Court ruling in *Eisenstadt v. Baird* that single women were given the same privilege. Today cost and the medicalized status of many contraceptives serve as significant barriers to accessing safe and effective birth control. Considering both the historic and current obstacles to birth control, it is not surprising that U.S. women have 1.6 times the number of births and three times the

number of abortions as women in Britain, Canada and the Netherlands (Samuels *et al.* 1994).

Making oral contraceptives (OCs) available without a prescription would reduce the barriers many women face – particularly those most at-risk of unplanned pregnancies – in obtaining birth control. By eliminating the requisite physician visit for OCs, the Food and Drug Administration (FDA) would provide women with a safe and effective birth control method at a lower cost and with no medical checkpoint. Increased access of this form of contraception would contribute to the reduction of incidences of unintended pregnancies and rates of abortion.

Oral contraceptives are one of the most effective forms of reversible contraception on the market. The birth control pill has a failure rate of .1 percent when used perfectly and a failure rate of between 3 percent and 6 percent for typical use (includes perfect and imperfect use patterns) (The Alan Guttmacher Institute 1998; Trussell *et al.* 1995). In comparison, condoms have a 2 percent failure rate with perfect use and a 16 percent failure rate with average use, and the diaphragm has a 6 percent failure rate with perfect use and an 18 percent failure rate with average use. Furthermore, oral contraceptives are the most popular form of reversible contraception with over 10.4 million women relying on the Pill as their preferred method of birth control. In comparison, 7.9 million women use male condoms and 720,000 women use diaphragms for contraception (The Alan Guttmacher Institute 1998).

The rationale for changing the prescription status of the birth control pill centers on the access barriers imposed by the requirement. Although the prescription regulation of drugs was implemented to protect consumers, Rx status of oral contraceptives may, in

fact, prevent women from experiencing the benefits of the product rather than protect them against the potential harms. The medicalized status of oral contraceptives add little to the quality or safety of the product and instead make it costlier for women to obtain an effective form of birth control. By lifting the prescription regulation of the pill and eliminating the need to see a physician, the government will remove a significant cost issue and increase women's access to the contraceptive. In addition, the psychological barrier of having to undergo a pelvic exam to obtain the Pill is removed reducing another access obstacle.

Benefit-Cost Analysis

While the issue of OTC oral contraceptives has been debated over the past decade as one line of attack against the high rates of unintended pregnancies and abortions in the U.S., no study has attempted to evaluate the impacts of switching the drug from an economic perspective. A cost-benefit analysis will help determine whether switching oral contraceptives to OTC status is more beneficial to women than continuing to regulate them as a prescription drug. In analyzing the Rx-to-OTC switch of oral contraceptives, I identify and attempt to measure the costs and benefits to all individuals with standing including sexually active women, pharmaceutical companies and society in general. By weighing the positive impacts against the negative impacts I can determine whether the OTC OC proposal improves the overall welfare of society.

Table 1 lists the benefits and costs that are likely to result from an Rx-to-OTC switch of oral contraceptives. To produce the most comprehensive evaluation of the policy proposal, I identify all potential impacts regardless of their ease or difficulty of measurement. Therefore, the table includes benefits and costs that I may not be able to

Table 1. Potential Impacts of Switching Oral Contraceptives To Over-the-Counter Status

Potential Benefits	*Potential Costs*
• Reduces price of obtaining the Pill - Increases access to women - Increases revenues to manufacturers • Eliminates opportunity cost of time spent with MD • Reduces unintended pregnancy rates and outcomes - Abortion - Miscarriages - Ectopic pregnancies - Term pregnancies • Protective health benefits/decreases risk of disease - Ovarian cysts - Ovarian Cancer - Benign breast disease - Endometrial cancer - Pelvic inflammatory disease • Removes psychological barrier of seeing MD • Reduces number of women psychologically affected by - unintended pregnancy/abortion	• Greater likelihood women at risk of adverse effects will use OCs - Women over age 35 who smoke • Increased incidences of disease from OC use - Myocardial infarction - Thrombotic stroke - Hemorrhagic stroke - Pulmonary Embolism/venous thromboembolism - Gallbladder disease • Higher failure rates due to misuse • Increased cost of marketing an OTC product • Concern that women will forego annual ob/gyn exams - Risk of undiagnosed disease - Low-income/Uninsured women fall through cracks of healthcare system • Higher out-of-pocket expenses for women

quantify for the analysis but whose impact should be recognized and considered nonetheless.

Potential Impacts of OTC Oral Contraceptives

The potential benefits associated with over-the-counter birth control pills stem from the wider distribution of the drug. A survey conducted by Louis Harris and Associates found that 20.4 percent of sexually active women who currently do not use the Pill would be very likely to switch to that form of birth control if it were available over-the-counter (1993).[1] With over 34 million sexually active women currently not using the Pill, a 20.4 percent increase would result in approximately 6.96 million new users for a total of 17.4 million women on the Pill.[2]

With more women using oral contraceptives, society would see large benefits in terms of lower incidences of pregnancies and their associated outcomes including abortions, miscarriages, ectopic pregnancies and term pregnancies. Women would also experience the psychological benefit of knowing they are protecting themselves with an extremely effective form of birth control and would be less likely to have to deal with the difficult issues associated with an unwanted pregnancy. In addition, a larger number of women would benefit from the protective health effects of oral contraceptives, which include decreased risk of ovarian cysts, ovarian cancer, benign breast disease,

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[1] I base all calculations of the potential increase in demand on the survey "Barriers to Pill Use" conducted by Louis Harris and Associates. To determine the increase in demand of oral contraceptives following a switch to OTC status, I relied on the question from the survey "If oral contraceptives, the Pill, became available at a pharmacy without a prescription would you be very likely, somewhat likely, not very likely or not at all likely to use them?" I used the conservative estimate of women who would be "very likely" to use an OTC OC in my calculations. The survey sample consisted of a national cross section of 807 women of childbearing age (between 18 and 44 years old) in the United States. The data were weighted to the U.S. Census Bureau's population parameters on age, race/ethnicity and education.

[2] Calculations are based on data from the Henry J. Kaiser Family Foundation, which reported that over 52 million women are sexually active in the United States. According to the Louis Harris and Associates survey, 65.6 percent of these women or 34.1 million women do not use the pill. This population of women is my base population for determining the number of potential new users if the Pill were to become OTC.

endometrial cancer and pelvic inflammatory disease. Women who choose to forego their annual pap smears or who see their physician more than once a year for prescription refills would also gain from the money and time they would save each year from not having to see their physician to renew or obtain their Rx birth control. Furthermore, those women who choose not to use oral contraceptives because of the required pelvic exam would no longer face this obstacle with OTC OCs. Women would not be the only group who would benefit from an Rx-to-OTC switch of the birth control pill. With approximately 6.96 million new users, pharmaceutical companies would see a large increase in revenues generated from the wider distribution of the drug

While OTC oral contraceptives would have a positive impact on society because of the wider use of a safe and effective form of birth control, an increase in the number of women using the Pill would also have some negative effects. Because women would be using the Pill without the guidance of a physician, women who are contraindicated for the drug, such as women who are over age 35 and who smoke heavily, may be more likely to use the Pill because they are unaware of their increased risk. In addition, with more women using the Pill, incidences of adverse health affects such as myocardial infarction, thrombotic stroke, hemorrhagic stroke, pulmonary embolism/venous thromboembolism and gallbladder disease are likely to increase.

Although pharmaceutical companies would see an increase in revenue from the wider distribution of OTC oral contraceptives, they would also face increased advertising costs associated with marketing an OTC drug. Because prescription drugs are mostly patented, companies rely heavily on doctors to perform most of the "marketing" of their products. When a drug becomes an OTC product, companies must increase their

marketing efforts to establish a brand name that can compete with products already available in the OTC market. Drug companies launching OTC oral contraceptives would need to support their products with substantial advertising to break into the OTC contraceptive market.

Some distributional issues arise with a switch of oral contraceptives to OTC status that may have significant costs for certain populations. If the birth control pill were to become available over-the-counter, most insurance companies would not cover the cost of the drug. As a result, women would pay higher out-of-pocket costs. In addition, many low-income women would no longer be able to receive subsidized birth control pills because of their OTC status. With the price of OCs between $20 and $32 per month, cost could become an issue for many low-income women.

Other costs associated with OTC oral contraceptives center on the concern that women would forego their annual gynecological exams if a physician visit were no longer required to obtain the Pill. According to the Louis Harris and Associates survey, approximately 12.1 percent of women would be "not at all likely" or "not very likely" to have an annual pelvic exam if they were not required to do so to obtain a prescription for oral contraceptives. Based on the estimate that 17.4 million women would use OTC birth control pills, about 2.1 million would not see their gynecologist every year for annual exams. These women would face an increased risk of serious, long-term health problems associated with undiagnosed reproductive conditions including sexually transmitted diseases and abnormal pap smears or breast exams. Many health care providers have also expressed concern that eliminating the physician visit would remove the only avenue

many women – particularly low-income women at risk of poor health – have into the health care system.

Estimating Benefits of OTC Oral Contraceptives

Reduction in Unintended Pregnancies

The potential reduction in unintended pregnancies is the most significant benefit that would result from an Rx-to-OTC switch of oral contraceptives. To determine the number of unintended pregnancies averted by the wider distribution of an OTC birth control pill, I estimate the number of unintended pregnancies that would occur in the 6.96 million potential new OTC OC users if they continue to use their current birth control method (including no method). To calculate this number I applied the percentage of unintended pregnancies in the population of sexually active women in the U.S. to the number of sexually active women who would choose to use the OTC birth control pill.[3] Close to 7 percent (6.92 percent) of sexually active women in the U.S. become pregnant unintentionally each year (Henry J. Kaiser Family Foundation 1996). Their pregnancies result from either not using birth control or using birth control that fails. Based on the national rate of unintended pregnancies, approximately 481,553 women in the population of potential new OTC OC users (6.96 million women) would become pregnant unintentionally.[4] Assuming a three percent failure rate for oral contraceptives (based on

[3] Estimates included in the analysis are rounded. All calculations, however, were computed using complete numbers.

[4] This estimate may understate the number of unintended pregnancies for the population of OTC OC users because the national rate of unintended pregnancies includes pregnancies that result from failed oral contraceptive use. The potential OC users do not currently use the Pill, which is an extremely effective form of contraception. I assume that because they would be willing to switch to the Pill if it were available OTC, they are currently using forms of reversible birth control (i.e. not sterilization) that are less reliable than the Pill. Using methods such as condoms, the diaphragm or IUDs, which have higher failure rates than the Pill, could increase the likelihood of unplanned pregnancies in that population.

Table 2. Medical Savings Associated with the Protective Benefits of Increased Over-the-Counter Oral Contraceptive Use

Health Condition	Reduced Incidences of Disease	Average Price	Best Estimate (in millions)
Ovarian Cysts	3,131.50	$1,313.50	$4.11
Benign Breast Disease	8,002.70	$669	$5.35
Endometrial Cancer	139.17	$15,373	$2.14
Ovarian Cancer	347.94	$10,749	$3.74
Pelvic Inflammatory Disease	11,152.00	$6,204	$69.19
Total Medical Savings			**$84.53**

data examining typical use of the Pill), a total of 467,105 of these pregnancies would be averted if all 6.96 million new OTC OC users start using the Pill.

To measure the benefits of these averted pregnancies, I estimate the cost savings associated with preventing the four possible pregnancy outcomes: abortion, miscarriage, ectopic pregnancy and term pregnancy. In a cost-effectiveness study of 15 different methods of contraception, Trussell *et al.* estimate the probability of each pregnancy outcome and the costs incurred from time of conception to outcome (1995).[5] Costs associated with abortions, miscarriages and ectopic pregnancies include the costs of all medical treatments and procedures from time of conception. Costs of term deliveries include prenatal care, delivery and newborn hospitalization, and other medical costs that end at the time of discharge from the delivery facility.[6] Table 2 presents the medical cost savings of preventing unintended pregnancies and their outcomes for the population of potential new OTC OC users. The total savings to society is $2.08 billion.

Protective Health Benefits

Use of oral contraceptives is associated with a reduction in the risk of several reproductive health conditions including ovarian cysts, ovarian cancer, benign breast disease, endometrial cancer and pelvic inflammatory disease (Trussell *et al.* 1995; Ashraf *et al.* 1994; Petitti 1994). To determine the protective benefit of the birth control pill, I calculate the reduction in incidences of disease based on rates of disease for non-users

[5] Trussell *et al.* estimate the probability of pregnancy outcomes for unintended pregnancies resulting from failure of each birth control method. These percentages vary slightly depending on the type of method used. For the sake of ease and clarity I have calculated costs using the rate of pregnancy outcomes that occurs for the majority of unintended pregnancies: 48.03 percent abortions; 12.28 percent miscarriages; one percent ectopic pregnancies; and 39.70 term pregnancies.

[6] The Trussell at al. study (1995) provides a range of costs depending on type of insurance provider (public versus private). I use an average cost based on these ranges in my analysis.

Table 3. Medical Savings from Averted Unplanned Pregnancies for Potential OTC Oral Contraceptive Users[1]

Pregnancy Outcome	Number of Outcomes	Average Price	Best Estimate (in millions)
Induced Abortion	219,679.69	$380.50	$83.59
Spontaneous Abortion/Miscarriage	57,360	$727	$41.70
Ectopic Pregnancy	4,671.05	$3,899.50	$18.21
Term Pregnancy	185,440.86	$10,430.50	$1,934.24
Total Savings			**$2,077.74**

[1] Calculations assume a three percent failure rate for oral contraceptives

and rates of disease for users for the population of potential OTC OC users.[7] In other words, I subtract the incidences of disease that would occur in the 6.96 million new users if they use OCs from the incidence of disease that would occur in this same population if they do not use OCs. To measure this benefit I calculate the cost savings associated with the reduction in disease based on average medical costs of each disease.[8] Table 3 presents the cost savings associated with the lower risk of each disease. Total medical costs saved due to the protective effect of OTC oral contraceptives equals $84.53 million.[9]

Time and Cost Savings from Physician Visit

Women who choose to forego their annual ob/gyn exams and women who see their physician more than once a year for prescription OC refills would experience a time and cost savings from the Rx-to-OTC proposal because they will no longer need to see a medical professional to obtain their birth control pills. I use data from the Louis Harris and Associates survey to determine the number of women who would experience this savings. The survey collected information on how often women see their doctors for prescription refills and what percentage of women would stop seeing their doctor annually if the Pill were available OTC.

[7] I use rates of disease for OC users and non-users from a summary of studies by Petitti (1994).

[8] Average medical cost for ovarian cysts and benign breast disease are based on cost ranges by insurance type (public versus private) provided by a study conducted by Trussell *et al.* (1995). I use data from a study conducted by Barnes *et al.* (1999) to estimate average medical costs for endometrial cancer. The average costs for ovarian cysts and pelvic inflammatory disease are based on pricing information from a study by Ashraf *et al.* (1994)

[9] I chose to look at the costs and benefits of disease in terms of medical expenses rather than lives saved or lost to avoid the controversy of monetizing the value of a life. When I quantified the numbers of lives saved and lost due to the switch of OCs to OTC status, I found that approximately 180 lives would be saved and 204 lives would be lost. Because these numbers are so close, I assume the protective benefit of lives saved due to OTC OCs directly offsets the risk of lives lost due to OTC OCs.

Using the survey data, I calculate that in the population of women who currently use the Pill (10.41 million women) 7.9 percent or 822,390 women see their physician four times a year for OC refills, 34.7 percent or 3.61 million see their physician two times a year for refills and 49.3 percent or 5.13 million see their physician once a year for refills. I assume the average cost of a physician's visit is $85 and that women will continue to see their physician at least once a year.[10] Women who see their physician four times a year will see a cost savings of $255 per year for a total savings of $209.71 million for the population. Women who see their physicians two times per year will save $85 for a total cost savings of $307.04 million.

The Louis Harris and Associates survey also found that 12.1 percent of OC users would stop seeing their physicians for annual exams if it were not required to obtain the Pill. If, based on the estimate of 17.36 million total OTC OC users (current users plus new users), 12.1 percent of them forego their annual physical, approximately 2.1 million women would save $85 for a total cost savings of $178.54 million. Overall, the savings to women who either stop seeing their physician annually or reduce their visits to one time per year equals about $695.29 million.

Women who see their doctor more than once a year to obtain OC refills or who forego their annual exam altogether also see an opportunity cost savings of time. In other words, the opportunity cost of time spent in the doctor's office to obtain refills would be saved if the Pill were available over-the-counter. To measure the value of this benefit, I assume the alternative use of the time spent in the physician's office would be work and that the value of time saved should, therefore, equal the average wage rate. Assuming the

[10] Average cost of a physician's visit is based on 1996 pricing data available at the Journal of the American Medical Association's Contraception Center at http://www.ama-assn.org/special/contra/support/ppfa/pill4.htm.

average wage rate is $12/hour and the average amount of time spent at the doctor's office is 1½ hours (including travel time), women who currently see their physician four times a year for OC refills would save 4.5 hours per year or $54 for a total opportunity cost savings of $44.41 million.[11] Women who see their doctors twice a year for refills would save 1.5 hours per year or $18 for a total opportunity cost savings of $64.02 million for the population.

Women who stop seeing their doctor for an annual physical following the switch of oral contraceptives to OTC status would also face an opportunity cost savings. Based on the estimate that 2.1 million women would forego their annual ob/gyn visit if it were not required to obtain the Pill, a total of 3.15 million hours could be spent working at a wage rate of $12 for a $37.81 million savings. Overall, the opportunity cost savings to women who either reduce or eliminate their physician visits equals $147.24 million.

Revenue to Pharmaceutical Companies

Manufacturers of oral contraceptives would see an increase in revenues from the product due to its wider distribution as an OTC drug. The prospect of higher revenues is a large factor behind most petitions to switch Rx drugs to OTC status. The higher revenues would come primarily from the increased user population, as pharmaceutical companies are unlikely to increase the price of oral contraceptives once OTC. Because of the competition of well-established OTC contraceptive brands such as Trojan condoms and the Today Sponge, introducing a higher priced oral contraceptive into the market could hurt a product's chances of capturing market share. The current price of oral contraceptives (between $20 to $32 per month) places the product at the high end of drug store brands, and OTC OCs would face price competition from both the Rx and OTC

[11] I assume women continue to see their physician at least once a year.

markets because of lower-priced alternatives in both categories. Furthermore, generic OCs whose Rx prices are 40 percent to 50 percent lower than brand-name OCs could introduce OTC alternatives at similarly discounted prices (Schondelmeyer and Johnson 1994).

To estimate the increase in revenues I assume a midpoint price for OCs of $26 per month for an annual cost of $312 per woman (de Boer *et al.* 1993; The Journal of the American Medical Association 1999; Dailard 1999). Based on the estimate of 6.96 million new users following the Pill's switch to OTC status, pharmaceutical companies would see an increase in revenue of about $2.17 billion.

Psychological Benefits

The psychological benefits associated with an Rx-to-OTC switch of oral contraceptives center on the lower levels of anxiety women would face knowing they are using a highly effective form of contraception. In addition with lower rates of unplanned pregnancies, fewer women would have to cope with the difficult and stressful decisions regarding an unwanted pregnancy. Finally, eliminating the requisite physician visit removes the psychological effects of having to undergo a pelvic exam, which becomes a significant access barrier to birth control pills for many women. While all of these benefits are important and deserve to be included in the cost-benefit analysis of this proposal, they are difficult to measure in monetary terms. To value the psychological impacts of the switch I would need to know women's willingness-to-pay for reduced anxiety and stress levels. Thus far, I am unaware of any study that attempts to value these benefits. Therefore, I will note their importance in the analysis with a "+" sign as a

way of underscoring their relevance even though they are not included in the final cost benefit calculations.

Estimating Costs of OTC Oral Contraceptives

Health Risks

Use of oral contraceptives is associated with an increased risk of certain adverse health events including myocardial infarction, thrombotic stroke, hemorrhagic stroke, pulmonary embolism/thrombophlebitis and gallbladder disease (Trussell *et al.* 1995; Ashraf *et al.* 1994; Petitti 1994).[12] Increasing the population of oral contraceptive users would increase the incidences of these events and the associated medical costs. To determine increased incidences, I compare the risk of disease to women who do not use oral contraceptives with the risk to those who do for the population of potential new users (6.96 million women).[13] To measure the increased risk in monetary terms, I calculate total medical costs associated with the increase in incidences of each disease based on an average medical cost of the disease.[14] Table 4 presents the costs associated with the increased risk of disease due to greater OC use. Total medical costs to society equal $44.62 million.

Cost to Women at Increased Risk of Adverse Events

With the switch of oral contraceptives to OTC status, women would be using the drug without guidance and direction from a physician. Some health care providers have

[12] Note regarding the inclusion of side effects: Because studies have found contradicting results regarding the net effect of oral contraceptives on breast and cervical cancer and the exact risk, if any, is not known, I have not included these diseases in the analysis. I have also only included side effects that require hospitalization or long-term medical care.

[13] Risk factors for each disease vary in the literature, so I determined an upper- and lower-bound estimate of risk and used the midpoint value in my calculations (Trussell *et al.* 1995; Petitti 1994; Ashraf, Arnold and Maxfield 1994; Strom *et al.* 1986).

[14] I calculate average expenses based on cost data provided by the Trussell *et al.* study. See note 8.

Table 4. Medical Costs Associated with Adverse Health Effects of Increased Over-the-Counter Oral Contraceptive Use

Adverse Health Events Due to OC Use	Increased Incidences of Disease	Average Price	Best Estimate (in millions)
Myocardial Infarction	347.96	$11,964.49	($4.16)
Thrombotic Stroke	1391.75	$11,141.26	($15.51)
Hemorrhagic Stroke	139.18	$11,141.26	($1.55)
Pulmonary Embolism/ Venous Thromboembolism	2783.54	$5,707.60	($15.89)
Gallbladder Disease	1739.71	$4,316.16	($7.51)
Total Medical Savings			**($44.62)**

expressed concern that women who are highly contraindicated for the drug may use it if a physician is not involved in the prescribing process to screen out at-risk groups. Specifically, society would see an increase in costs associated with adverse events such as myocardial infarction, stroke and pulmonary embolism in women over the age of 35 who smoke 15 or more cigarettes per day.[15] To measure this increased risk, I estimate the number of women among the 6.96 million new users who would be contraindicated for OC use and calculate the added cost to society based on their increased risk of adverse events.

Data on the use patterns of oral contraceptives reveal that 4.7 percent of all users are between the ages of 35 and 44 (Schiff 1999). Assuming the risk of contraindication will affect only those who would never be required to see a physician for OCs (i.e. the 6.96 million new users), only 327.066 are between 35 and 44 years of age. According to this same data, one quarter of women who use oral contraceptives smoke and 50 percent of smoking OC users smoke heavily. Based on the smoking prevalence of OC users, I estimate that 81,766 new OC users would smoke and half of these women or 40,883 would smoke 15 or more cigarettes a day. According to a study on the benefits and risks of OC use, experiencing a CVD incident is the primary risk older women face if they combine smoking and OC use (Schwingl *et al.* 1999). The risk of having a fatal CVD incident (includes MI, stroke and pulmonary embolism) increases from .001 percent among OC non-users in this age group to .02 percent among OC users who smoke in this

[15] Although other groups of women are contraindicated for OC use, these women are either on other drugs that could cause adverse effects when used with OCs or have health conditions that could cause adverse effects when using OCs. In either case, however, I assume these women are under the guidance of a physician who would explain to them the risk factors of using oral contraceptives. Older women who smoke are the only group for whom medical guidance is not anticipated and who would, therefore, be at risk of self-prescribing OCs without knowing the consequences.

age group. I estimate the increase in incidents for the population of OC users aged 35-44 years old who smoke heavily to be about 7.6 if the Pill were to become available OTC. Based on an average cost of CVD equal to $11,020.5, the total cost to this population would be $83,755.8.[16]

Costs of Foregone Ob/Gyn exam

Many health professionals have expressed concern that switching the birth control pill to over-the-counter status would cause many women to stop seeing their health care providers for their annual gynecological exam. As noted earlier, an estimated 2.1 million women out of a total of 17.36 million OC users would stop seeing their physician every year if the Pill were available OTC. Because these women no longer see their ob/gyns annually, a dangerous delay in diagnosis and treatment of health problems such as STDs or abnormal pap smears could lead to more serious and costly health problems including pelvic inflammatory disease or ovarian cysts. In addition, undiagnosed precursor conditions such as cervical dysplasia, which is often detected with pap smears, could develop into advanced stages of cancer if not identified and treated promptly.

The cost of foregoing annual pelvic exams is difficult to quantify, however, because I cannot predict with certainty the percentage of long-term health problems that could be prevented with annual exams or the cost savings that would result from early intervention in a disease. I can, however, attempt to measure the cost by inflating the risk factor of serious health problems including ovarian cysts, ovarian cancer, endometrial cancer, breast cancer and cervical cancer in this population of women. For this analysis, I increase the risk two-fold. To measure the increased risk in long-term health problems associated with STDs, I take a similar approach. Because pelvic inflammatory disease is

[16] I derived average cost from pricing information in the study conducted by Ashraf (1994).

Table 5. Medical Costs Associated with Increased Risk of Undiagnosed Disease in Women Who Use Over-the-Counter Oral Contraceptives and Forego Annual Physical Exa

Adverse Health Condition	Increased Incidences of Disease[1]	Best Estimate (in millions)
Ovarian Cysts	630.13	($0.828)
Ovarian Cancer	210.04	($2.26)
Endometrial Cancer	84.02	($1.29)
Breast Cancer	20,458.27	($317.43)
Cervical Cancer	2,814.59	($43.67)
Pelvic Inflammatory Disease	6,721.40	($41.70)
Total Medical Savings		**($407.18)**

[1]Increased incidences are due to delayed diagnosis and treatment of precursor health conditions

the most common and most serious health consequence of undiagnosed STDs, I double the risk of PID in the population of OC users who stop seeing their ob/gyns regularly.[17] I use the same average cost of disease as I did in the above analyses of OC health effects.[18] Table 5 presents the medical costs associated with the increase in reproductive diseases due to undiagnosed problems. The total cost to society equals $407.18 million.

Marketing Costs of OTC Oral Contraceptives

When a drug switches from prescription to over-the-counter status, pharmaceutical companies must invest more in advertising and promotional support to market the drug. Historically with prescription drugs, companies have relied primarily on physicians to sell their drugs because regulations regarding consumer advertising were extremely stringent. As a result, advertising and promotional support for Rx products has been limited to professional detailing by pharmaceutical sales forces, ads in professional journals and educational brochures for physician's offices. Although recent changes in FDA advertising policy give companies more flexibility in advertising Rx drugs directly to consumers, firms producing oral contraceptives have not significantly increased their ad/promo support.[19]

Unlike with Rx drugs, a launch of an OTC product requires significant advertising and promotional support because companies must rely on the consumer to make their own purchasing choices. Visibility of the drug in consumer magazines, in television ads

[17] I calculate incidences of disease of PID, cervical cancer and cysts, ovarian cancer and endometrial cancer based on risk factors in OC users from Petitti's review of the literature (1994). I derive incidences of breast cancer using risk data from the American Cancer Society (1997) and incidences of cervical cancer using risk data from a study conducted by Coker, Harlap and Fortney (1993).

[18] I base my average cost for breast and cervical cancer on a study on the cost of care for patients in cancer clinical trials (Fireman *et al.* 2000). This study examined the medical costs for patients enrolled in cancer clinical trials including 12 breast cancer trials. I use the costs estimated for the control subjects as my estimate in the analysis. This cost is likely to be much higher than the actual cost for cervical cancer and may be slightly overstated for breast cancer.

[19] Personal communications with Michael McCaughan, Editor-in-Chief, FDC Reports "The Pink Sheet."

and at point-of-purchase will help build a brand name that consumers will begin to recognize and buy. To estimate the amount of marketing support companies would spend to launch OTC oral contraceptives, I examine the ad/promo budgets of the OTC launch of an analogous good – feminine yeast infection products. Yeast infection products are an appropriate analogous good for several reasons. First, the product targets a similar all-female population. Second, concerns regarding the safe and effective use of the yeast infection products without the guidance of a physician are similar to those regarding OC consumer use. Manufacturers of yeast infection products were required to address these concerns with additional educational/informational materials at a higher promotional cost. FDA would most likely mandate a similar educational campaign regarding use of OTC OCs if an Rx-to-OTC switch were approved. Finally, although Rx OCs have a larger market than Rx yeast infection products, the OTC market for contraceptives is similar in size to the OTC yeast infection market.

The two categories of drugs, however, are not analogous in one important way – the switch of Rx yeast infection products to OTC status created a category of drugs that was not already available to the consumer market. In this case, the switch of OCs to OTC status may be more akin to the switch of prescription gastrointestinal drugs like Pepcid AC and Zantac 75 into the OTC antacid drug market. These drugs were launched into a competitive drug store market that included well-established brand names like Tums and Pepto-Bismol. Aware of the stiff competition in the OTC market, manufacturers of Pepcid AC and Zantac 75 devoted significant advertising and promotional funds to the OTC launch of their products.

To estimate the amount of marketing support OTC OCs would likely receive, I looked at the average advertising budget for the two categories of analogous goods as a percentage of the overall OTC market for that category.[20] For example, the average advertising budget for the launch of three yeast infection products – Gyne Lotrimin, Monistat and Mycelex-7 – was $12.5 million ("Ortho's OTC Monistat 7" 1991; "Schering's Femcare" 1992; "Mile's Mycelex-7" 1993). Total sales in the feminine yeast infection market for 1992 were $295 million ("Mile's Mycelex-7" 1993). Manufacturers of these products spent approximately 4 percent of the overall yeast-infection market on marketing support for their products. The average advertising budget for the Rx-to-OTC launches of the antacid products was about $50 million (Bittar 1999). Total sales for the OTC gastrointestinal market following the switches equaled about $1 billion ("OTC Switches" 1996). The manufacturers of Pepcid AC and Zantac 75 spent approximately 5 percent of the overall antacid market on advertising support for their products. Following this equation, total sales for the OTC contraceptive market equaled $268.8 million in 1999 ("OTCs: Contraceptives." 2000). Using a midpoint percentage of sales value of 4.5 percent, I estimate that manufacturers will spend approximately $12.1 million to launch oral contraceptive brands into the OTC market. According to the *Physician's Desk Reference*, 30 different brand name OCs are available in the prescription market. If I assume that the manufacturers of all 30 brands choose to launch OTC versions, then the

[20] Because overall sales for each brand were not available, I had to rely on ad spend as a percentage of the overall market for the category of good rather than for individual brands.

total cost in increased marketing of OTC OCs to the pharmaceutical industry would be $362.88 million.[21]

Costs to Low-Income Women

Some health care providers object to over-the-counter oral contraceptives because they fear a switch to OTC status would have a negative impact on low-income women. Health professionals have expressed concern that low-income women and women without health insurance who have regular interactions with the health care system to obtain birth control pills would either lose access to free or subsidized care or choose to forego regular physicals and fall through the cracks of the health care system. In addition, providers are concerned that OTC status of OCs may actually create barriers to birth control access for disadvantaged women. Currently, some insurance companies reimburse prescription OCs. Once the Pill is OTC, however, insurance companies are less likely to cover the product. Without insurance coverage, women will pay larger out-of-pocket costs, which could impose serious obstacles for low-income women. In addition, many uninsured, low-income women are able to obtain subsidized OCs from public clinics. These subsidies, however, are unlikely to continue if the product becomes available over-the-counter. The costs to low-income women are difficult to measure and should not be valued based on efficiency goals. But because they are important to the overall conclusion of the study, I represent them in the analysis with a "–" sign despite my inability to quantify their value.

[21] It is unlikely that all 30 Rx brands will be launched in the OTC market. However, because I have no way of knowing exactly how many would be switched to OTC status, I assume that all 30 brands will have drug store versions, resulting in an estimated cost equal to $362.88 million.

Results

The net benefit to society of a proposed Rx-to-OTC switch of oral contraceptives is overwhelming, equaling $2.06 billion dollars (see Table 6). Total benefits to society would approximate $5.18 billion, but would be offset by $3.11 billion in costs. The majority of this benefit would be derived from the $2.08 billion in medical savings from prevented unplanned pregnancies. Society would save $1.93 billion in medical costs from term pregnancies, the most expensive outcome of an unplanned pregnancy (see Table 2). Averting unplanned pregnancies would also reduce the rates of abortion, which would save about $83.59 million in medical costs. Finally, society would save $41.7 million in averted miscarriages and $18.21 million in averted ectopic pregnancies with OTC OCs.

An additional $842.53 million in savings to society would come from the monetary and time costs many women would stop paying once distribution of the Pill was released from the direction of a physician ($695.29 million and $147.24 million, respectively). Society also would save about $84.53 million in medical costs from the protective health benefit of the Pill (see Table 3). In particular, OC use would substantially reduce the incidences of pelvic inflammatory disease resulting in a cost savings of $69.19 million. In addition, the pill would have a protective effect against benign breast disease and ovarian cysts resulting in medical savings of $5.35 million and $4.11 million, respectively. Society also would save a total of $5.88 million in medical costs from lower incidences of ovarian ($3.74 million) and endometrial ($2.14 million) cancers.

Table 6. Overall Net Benefits to Society from OTC Oral Contraceptives

Benefits and Costs to Society	Best Estimate (in millions)	Sensitivity Analysis (in millions)
Benefits of OTC OCs		
Increase in revenue for producers	$2,171	$2,171
Saved monetary cost of MD visit	$695.29	$695.29
Saved opportunity cost of time	$147.24	$147.24
Reduction in unintended pregnancies and their outcomes	$2,078	$1,715.60
Health benefits associated with OC use	$84.53	$84.53
Lower anxiety levels associated with OC use	+	+
Total Savings	$5,176	$4,813.66
Costs of OTC OC Use		
Cost of OCs to consumers	($2,171)	($2,171)
Health risks associated with OC use	($44.62)	($44.62)
Increased risk of undiagnosed disease	($407.18)	($814.36)
Higher incidences of adverse events in at-risk women	($83.76)	($0.532)
Increased cost of marketing OTC OCs	($405)	($405)
Cost to low-income women	-	-
Total Costs	($3,111.56)	($3,436)
Net Benefit to Society	**$2,064.24**	**$1,378**

Although I was unable to measure the psychological benefit of OTC OCs, I include it in the discussion of benefits to highlight its importance when considering implementation of the policy. Women who use the pill would experience lower levels of anxiety knowing they are relying on one of the most effective forms of birth control. More importantly, however, OTC access to this method would eliminate the substantial psychological barriers many women at-risk of unplanned pregnancies often feel toward the pelvic exam. Finally, by reducing the incidences of unplanned pregnancies, fewer women would be faced with the difficult and stressful decisions regarding the outcome of that pregnancy.

While pharmaceutical companies would benefit significantly from an OTC birth control pill due to an increase in total revenue of about $2.17 billion, this gain would be directly offset by the cost to consumers of having to pay for the Pill.[22] However, basing this analysis on revenue data slightly understates the overall gain to society because it cannot measure the social surplus associated with the proposal.

Although in monetary terms the positive impacts of an OTC oral contraceptive substantially outweigh the negative impacts, the costs do reduce the benefits by over half (see Table 6). In the sensitivity analysis I will explore whether higher risk factors would affect these results enough to completely offset the benefits. In particular, I will look at whether higher risk factors for women who forego their annual ob/gyn exams will affect the results since the majority of the costs ($407.18) come from medical expenses related to undiagnosed diseases.

[22] Insurance companies would also gain if OCs were switched to OTC status because they would no longer cover the Pill in prescription plans. This gain, however, is only a transfer from insurers to women and is, therefore, not included as a separate benefit to society.

Delayed diagnosis and treatment of precursor health conditions and early stage cancers would be the most costly to society. Medical costs of breast cancer in this population would equal about $317.43 million dollars and cervical cancer costs would approximate $43.67 million (see Table 5). Society would also experience a loss in medical costs of about $41.7 million from the increased number of STDs that would remain undiagnosed and lead to pelvic inflammatory disease. Finally, the increased incidences in ovarian cysts, ovarian cancer and endometrial cancer would result in medical costs of $828,000, $2.26 million and $1.29 million respectively.

Increased risk of adverse health events in the general population of OTC OC users would cost society $44. 62 million, which is only about half the amount society would save in medical costs from the protective effect of OC use (see Table 4). Medical expenses related to pulmonary embolism/venous thromboembolism and thrombotic stroke would be the most costly to society at $15.51 million and $15.89 million respectively. Society would face costs of about $7.51 million due to the increased incidences of gallbladder disease and $4.16 million from increased numbers of women experiencing myocardial infarctions. The increased risk of hemorrhagic stroke would cost society about $1.55 million. The higher risk of adverse events among women who are contraindicated for OC use would add about $83.76 million in costs to society. These costs would consist of the medical expenses related to CVD events of women aged 35-44 years of age who smoke heavily and use OCs.

The expense of marketing an OTC birth control pill is the second highest cost in the analysis. The pharmaceutical industry would face costs of about $405 million to support the marketing of an OTC oral contraceptive launch. These costs would consist of

advertising and promotional support of OTC OCs in a market that is dominated by cheaper, brand name OTC alternatives like Trojan condoms.

Society would also face additional costs that cannot and should not be measured by the monetary standard of a dollar, but should nonetheless be considered in the policy making process. Low-income women could face higher costs following an Rx-to-OTC switch of the Pill because insurance is likely to stop covering the method and subsidized prices would no longer be available. In addition, many disadvantaged women who are at-risk of poor health will stop using the health care system if they no longer need to for OC refills. Without regular contact with health care providers, these women are likely to fall through the cracks of the system and stop receiving needed preventive and curative medical care.

Sensitivity Analysis

Because of the uncertainty of some of the measures of my variables, I conducted a sensitivity analysis to determine the robustness of my results. In the analysis I adjust the estimates of three key variables: rates of averted unplanned pregnancies, rates of disease for women who forego their annual exams and risk of adverse events among women contraindicated for OC use.

I adjusted the estimate of averted unplanned pregnancies by inflating the failure rate associated with oral contraceptive use. In the initial analysis, I use a failure rate of 3 percent, which is consistent with the literature. Failure rates are likely to increase, however, because use of the drug will no longer be under the direction of a physician. Women may not understand the importance of taking the Pill at the same time every day,

and they may not know what to do when a dosage is missed or when backup contraception is needed. Without guidance from a health care provider, women are more likely to misuse the drug resulting in a lower efficacy rate. Because the medical savings of prevented unplanned pregnancies is such a substantial benefits to society, I increase the failure rate to 20 percent to get an idea of the impact this variable has on the overall results. With a failure rate of 20 percent, the number of unplanned pregnancies that would be averted is reduced to 385,241.6. Of these pregnancies, 181,179.12 would end in abortion at a total cost to society of $68.94 million. About 47,307.67 would end in miscarriage at a cost of $34.39 million and 3,852.42 would be ectopic pregnancies at a cost of $15.02 million. Finally, 152,940.92 of these unplanned pregnancies would be brought to term with costs equally about $1.60 billion. With an 80 percent success rate for oral contraceptives, which is significantly lower than reported in the literature, the medical savings to society would still equal $1.71 billion.

Because I have no estimates of the costs of foregoing an annual pelvic exam, I used an inflated risk factor of disease to determine the medical expenses of certain reproductive conditions in the population of women who would stop seeing their doctor following the switch of OCs to OTC status. These expenses comprise the highest costs of the Rx-to-OTC OC proposal. Because I am uncertain of an exact estimate of costs, however, I inflate the risk even more in the sensitivity analysis to determine how influential this category of costs are on my final analysis. By doubling the initial risk factors (those reported in the literature), the costs equal $407.18 million. If I inflate these risk factors again twofold, medical costs would increase to $814.36 million.

Without physician control of oral contraceptives, older women who smoke – a population of women who are contraindicated for the drug – may be more likely to use the pill, increasing the incidences of CVD events. In the initial analysis, I estimate the population of older smokers who use OCs based on current use data. If OCs become available over-the-counter, the population of older smokers using the Pill is likely to increase. In the sensitivity analysis, I double this population of women to 81,799.46 and increase the risk to .06 percent, the upper bound reported in the literature (Sherif 1999). Based on these data, an additional 48.28 older women who smoke and use OCs would experience a CVD event at a total cost to society of $532,089.74.

Results of Sensitivity Analysis

The sensitivity analysis of an Rx-to-OTC switch of oral contraceptives produced results that confirm the initial cost-benefit analysis and demonstrate the robustness of the results. With net benefits of $1.38 billion the positive impacts still substantially outweigh the negative impacts despite the increase in the failure rate and inflated risk factors. As with the initial analysis, the medical savings associated with averted pregnancies comprise the majority of the benefits even after adjusting for a higher OC failure rate. The higher rates of disease due to delay in diagnosis and the larger population of contraindicated OC users did not result in costs that offset substantially the overwhelming benefit derived from averted unplanned pregnancies.

Recommendations

Based on the cost-benefit results of a proposed Rx-to-OTC switch of oral contraceptives, I recommend FDA approve the OTC status of the birth control pill. The

public health benefits associated with reduced rates of unplanned pregnancies and abortions as well as the cost savings to society would substantially outweigh any risks of increased and undirected use of oral contraceptives. In addition, OTC oral contraceptives would save some women both time and money by eliminating the required physician's visit. Finally, the protective benefit of oral contraceptives reduces the risk of certain diseases, thereby decreasing medical costs to society.

If an OTC birth control pill were approved, I would also recommend the federal government consider several complementary policies to address any potential problems resulting from the switch. For example, FDA should require that OC manufacturers develop and sponsor an extensive educational campaign emphasizing the importance of annual pelvic exams. Such a campaign would identify the risks women face when foregoing annual exams and help reduce the social costs associated with increased incidences of disease from this outcome. The campaign could also highlight groups of women who are contraindicated for OC use and are at higher risk of adverse events. The government should also mandate Medicaid coverage of over-the-counter birth control pills and allow public clinics to continue providing low-cost OCs regardless of their drug status. In addition, the government should require that all insurance companies include OTC OCs in their prescription plans. Finally, I would recommend that the federal government develop a comprehensive health care plan to address health providers' concerns regarding the health of disadvantaged women, rather than rely on the secondary effects of a policy such as requisite pelvic exams for Rx OCs to keep low-income women in contact with the health care system.

The cost-benefit study of the Rx-to-OTC switch of oral contraceptives was conducted for the Institute for Women's Policy Research (IWPR). IWPR is a public policy

research organization dedicated to informing and stimulating the debate on public policy issues of critical importance to women. The Institute has conducted research on access to health insurance, the costs and benefits of preventive health services and the costs of domestic violence. IWPR Research Fellow Holly Mead has an extensive background in the area of women's health and the Food and Drug Administration, beginning her career as a reporter and editor for FDC Reports, which publishes a number of trade journals covering the FDA. She is now pursuing her PhD in public policy with an emphasis on women's health.

Works Cited

The Alan Guttmacher Institute. *Facts in Brief: Contraceptive Use*. New York: The Alan Guttmacher Institute, 1998

American Cancer Society. *Breast Cancer Facts and Figures: Who Is at Risk of Developing Breast Cancer*. Atlanta, Ga.: American Cancer Society, 1997. Available at http://www.cancer.org/statistics/97bcff/risks.html.

Ashraf, Talat, Sharon Arnold, Myles Maxfield. "Cost-Effectiveness of Levonorgestrel Subdermal Implants: Comparison with other Contraceptive Methods Available in the United States." *The Journal of Reproductive Medicine* 39, No. 10 (Oct. 1994): 791-798.

Barnes, M.N., P.Y. Roland, M. Straughn, L.C. Kilgore, R.D. Alvarez, E.E. Partridge. "A Comparison of Treatment Strategies for Endometrial Adenocarcinoma: Analysis of Financial Impact." *Gynecologic Oncology* 73, No. 3 (Sept. 1999): 443-447.

Bittar, Christine. "First Generation Tackles Second Generation Challenge." *Brandweek*, 21 June 1999, S58.

Coker, Ann, Susan Harlap, and Judith Fortney. "Oral Contraceptive and Reproductive Cancers: Weighing the Risks and Benefits." *Family Planning Perspectives* 25, No. 1(January/February): 17-21.

Dailard, Cynthia. "U.S. Policy Can Reduce Cost Barriers to Contraception." *Issues in Brief*. New York: Alan Guttmacher Institute, 1999.

De Boer, A., R.M. Herings. "Editorial: Oral Contraceptives without Prescription." *Lancet* 342, no. 8877 (Oct. 1993): 993.

Family Health International. "What are the Benefits and Risks of Combined Oral Contraceptives." New York: Family Health International, 1999. Available at http://www.ama-assn.org/special/contra/support/educate

Fireman, Bruce, Louis Fehrenbacher, Elisabeth Gruskin and Thomas Ray. "Cost of Care for Patients in Cancer Clinical Trials." *Journal of the National Cancer Institute* 92 (January 19, 2000): 136-142.

Journal of the American Medical Association/Planned Parenthood Federation of America. "You and the Pill." *Contraception Information Center*. Online. Internet. 1996. Available at http://www.ama-assn.org/special/contra/support/ppfa/pill4.htm.

Henry J. Kaiser Family Foundation. *Contraception: Trends in Use, Safety and Effectiveness*. Menlo Park, Ca: Henry J. Kaiser Family Foundation, 1996.

Available at http://www.kff.org.

Louis Harris & Associates. *Barriers to Pill Use.* Chapel Hill, N.C.: Institute for Research in Social Sciences, 1993. IRSS Study Number S932008. Available at *http://www.irss.unc.edu.*

"Mile's Mycelex-7 Finishes 1992 with 14% Unit Share." *FDC Reports "The Tan Sheet"* 1 March 1993, 14-15.

"Ortho's OTC Monistat 7 Will Be on Pharmacy Shelves by Mid-March." *FDC Reports "The Pink Sheet"* 4 March 1991, T&G-1 – T&G-2.

"OTCs: Contraceptives." *Chain Drug Review* 3 Jan. 2000, 40.

"OTC Oral Contraceptive Benefit to "Subgroups" Outweighed by Risk to Adolescents." *FDC Reports "The Tan Sheet"* 6 June 1994, 6-8.

"OTC Switches Raise Great Expectations." *Canadian Business and Current Affairs: Pharmicist News* 4, No. 1 (February 1996): 23, 27.

Petitti, Diana. "Safety of Birth Control Pills." In *The Pill: From Prescription to Over the Counter.* Ed. Sarah Samuels and Mark Smith, 77-116. Menlo Park, Calif.: the Henry J. Kaiser Foundation, 1994.

Samuels, Sarah, Jeff Stryker and Mark Smith. "Over-the-Counter Birth Control Pills: An Overview." In *The Pill: From Prescription to Over-the Counter,* Ed. Sarah Samuels and Mark Smith, 1-20. Menlo Park, Ca.: Henry J. Kaiser Family Foundation, 1994.

"Schering's Femcare OTC Antifungal Discounted 20% to Gyne-Lotrimin." *FDC Reports "The Pink Sheet"* 15 June 1992, T&G-4 – T&G-5.

Schiff, Isaac. "Introduction." *American Journal of Obstetrics and Gynecology* 180, no. 6 part 2 (June1999): S341-S342.

Schondelmeyer, Stephen and Judy Johnson. "Economic Implications of Switching from Prescription Status." *The Pill: From Prescription to Over-the Counter.* Ed. Sarah Samuels and Mark Smith, 189-236. Menlo Park, Ca.: Henry J. Kaiser Family Foundation, 1994.

Schwingl, Pamela, et al. "Estimates of the Risk of Cardiovascular Death Attributable to Low-Dose Oral Contraceptive in the United States." *American Journal of Obstetrics and Gynecology* 180 (Jan 1999): 241-249.

Sherif, Katherine. "Benefits and Risks of Oral Contraceptives." *American Journal of Obstetrics and Gynecology*180, no. 6 part 2 (June1999): S343-S348.

Trussell, James, Joseph Leveque, Jaqueline Koenig, Robert London, Spencer Borden, Joan Henneberry, Katherine LaGuardia, Felicia Stewart, George Wilson, Susan Wysocki, Michael Strauss. "The Economic Value of Contraception: A Comparison of 15 Methods." *American Journal of Public Health* 85, no. 4 (April 1995): 494-503.